Atty Dkt No. PP1393.002
(CHIR-1393/01US)

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In the Application of BARCHFELD et al.

Confirmation No. 8826

Serial No.: 09/044,696

Art Unit: 1645

Filed March 18, 1998

Examiner: DEVI, SARVAMANGALA J N

Title: DETOXIFIED MUTANTS OF BACTERIAL ADP-RIBOSYLATING TOXINS AS PARENTERAL ADJUVANTS

U.S. PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
SD	A-1	4,328,209	May 4, 1982	Finkelstein et al.	424	92	
SD	A-2	4,428,931	January 31, 1984	Tolman et al.	424	87	
SD	A-3	4,666,837	May 19, 1987	Harford et al.	435	68	
SD	A-4	4,892,827	January 19,1990	Pastan et al.	435	193	
SD	A-5	4,925,792	May 15, 1990	Rappuoli	435	69.1	
SD	A-6	4,935,364	June 19, 1990	Kaper et al.	435	172.3	
SD	A-7	5,032,398	July 16, 1991	Kaslow	424	92	
SD	A-8	5,085,862	February 4, 1992	Klein et al.	424	92	
SD	A-9	5,182,109	January 1993	Tamura et al.	424	92	
SD	A-10	5,221,618	June 1993	Klein et al.	435	69.1	
SD	A-11	5,244,657	September 1993	Klein et al.	424	88	
SD	A-12	5,332,583	July 26, 1994	Klein et al.	424	190.1	
SD	A-13	5,358,868	October 25, 1994	Klein et al.	435	243	
SD	A-14	5,427,788	June 1995	Rappouli et al.	424	190.1	
SD	A-15	5,433,945	July 18, 1995	Klein et al.	424	185.1	
SD	A-16	5,601,827	February 11, 1997	Collier et al.	424	190.1	
SD	A-17	5,668,255	September 16, 1997	Murphy	530	350	
SD	A-18	5,747,028	May 5, 1998	Calderwood et al.	424	93.2	
SD	A-19	5,770,203	June 23, 1998	Burnette et al.	424	190.1	
SD	A-20	5,773,600	June 30, 1998	Burnette	536	23.7	

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Title: DETOXIFIED MUTANTS OF BACTERIAL ADP-RIBOSYLATING TOXINS AS PARENTERAL ADJUVANTS

SD	A-21	5,785,971	July 28, 1998	Rappouli et al.	424	190.1	
SD	A-22	5,786,189	July 28, 1998	Locht et al.	435	172.3	
SD	A-23	5,856,122	January 5, 1999	Read et al.	435	69.1	
SD	A-24	5,874,088	February 23, 1999	Mekalanos	424	200.1	
SD	A-25	5,874,287	February 23, 1999	Burnette et al.	435	252.3	
SD	A-26	5,882,653	March 16, 1999	Kaper et al.	424	261.1	
SD	A-27	5,889,172	March 30, 1999	Pizza et al.	536	23.7	
SD	A-28	5,925,546	July 20, 1999	Pizza et al.	435	69.3	
SD	A-29	5,942,418	August 24, 1999	Loosmore et al.	435	69.1	
SD	A-30	5,961,970	October 5, 1999	Lowell et al.	424	93.1	
SD	A-31	5,965,385	October 12, 1999	Read et al.	435	69.1	
SD	A-32	5,977,304	November 2, 1999	Read et al.	530	350	
SD	A-33	5,985,284	November 16, 1999	Lowell	424	234.1	
	A-34	6,019,982	February 1, 2000	Clements	424	236.1	
	A-35	6,030,624	February 29, 2000	Russell et al.	424	200.1	
	A-36	6,033,673	March 7, 2000	Clements	424	236.1	
	A-37	6,019,982	February 1, 2000	Clements	424	236.1	
SD	A-38	6,129,923	October 1999	Doidge et al.	424	234.1	

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Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub Class	Translation YES	Translation NO
SD	B-1	WO 90/14837	December 13, 1990	PCT				
	B-2	WO 92/22326	December 23, 1992	PCT				
	B-3	WO 94/01533	January 20, 1994	PCT				
	B-4	WO 95/03824	February 9, 1995	PCT				
	B-5	WO 95/09649	April 13, 1995	PCT				
	B-6	WO 00/18434	April 6, 2000	PCT				
	B-7	EP 0 222 835B1	September 28, 1994	EPO				
	B-8	EP 0 396 964	September 6, 1999	EPO				
	B-9	EP 0 462 534	December 27, 1991	EPO				
SD	B-10	EP 0 688 868	December 27, 1995	EPO				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Exam. Init.	Ref. Desig.	Description
SD	C-1	Anderson et al., "Immunogens Consisting of Oligosaccharides from the Capsule of *Haemophilus Influenzae* Type b Coupled to Diphtheria Toxoid or the Toxin Protein CRM197," *J. Clin. Invest.* 76:52-59 (1985)

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Exam. Init.	Ref. Desig.	Description
SD	C-2	Anderson, "Antibody Responses to haemophiles Influenzae Type b and Diptheria Toxin Induced by Conjugates of Oligosaccharides of the Type b Capsule with the Nontoxic Protein CRM $_{197}$," *Inf. & Immun.* 39(1):233-238 (1983)
	C-3	Bartley et al., "Pertusis Holotoxoid Formed *in vitro* with a Genetically Deactivated S1 Subunit," *PNAS USA* 86:8353-8357 (1989)
	C-4	Bennett et al., "A Comparison of Commerically Available Adjuvants for Use in Research," *J. Immunol. Methods* 153:31-40 (1992)
	C-6	Black et al., "Construction and Characterizations of Bordetella pertussis Toxin Mutants," *Infection & Immununity* 55(10):2465-2470 (1987)
	C-7	Boslego et al., "Gonorrhea Vaccines," *Vaccines and Immunotherapy* Chapter 17, pp 211-223 (1991)
	C-8	Bowie et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," *Science* 247:1306-1310 (1990)
	C-9	Brandtzaeg, "Overview of the Mucosal Immune System," *Current Topics Microbiol. & Immunol* 146:13-25 (1989)
	C-10	Burnette, "AB$_5$ ADP-Ribosylating Toxins: Comparative Anatomy and Physiology," *Structure* 2(3):151-158 (1994)
	C-11	Burnette, "Perspectives in Recombinant Pertussis Toxoid Development," *Vaccine Research & Developments* Chapter 6:143-193 (1992)
	C-12	Burnette, "The Advent of Recombinant Petussis Vaccines," *Biotechnol.* 8:1002-1005 (1990)
	C-13	Carbonetti et al., "Intracellular Delivery of Cytolytic T-Lymphocyte Epitope Peptide by Pertussis Toxin to Major Histocompatibility Complex Class I Without Involvement of the Cytosolic Class I Antigen Processing Pathway," *Infection & Immunity* 67(2):602-607 (1999)
SD	C-14	Czerkinsky, C. et al., "Oral Administration of a Streptococcal Antigen Coupled to Cholera Toxin B Subunit Evokes strong Antibody Responses in Salivary Galnds and Extramucosal Tissues," *Infect. & Immun.* 57:1072-1077 (1989)

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Exam. Init.	Ref. Desig.	Description
SD	C-15	Dallas, W.S. et al, "Cistrons Encoding *Escherichia coli* Heat-Labile Toxin," *J. Bacteriol.* 139:850-858 (1979)
	C-16	de Haan et al., "Mucosal Immunogenicity of the *Escherichia coli* Heat-Labile Enterotoxin: Role of the A Subunit," *Vaccine* 14(4):260-266 (1996)
	C-17	Del Giudice & Rappuoli, "Genetically Derived Toxoids for use as Vaccines and Adjuvants," *Vaccine* 17:S44-S52 (1999)
	C-18	Dente et al., "pEMBL: A New Family of Single Stranded Plasmids," *Nuc. Acids. Res.* 11(6):1645-1655 (1983)
	C-19	Dertzbaugh, M.T. et al., "Reduction in Oral Immunogenicity of Cholera Toxin B Subunit by N-terminal Peptide Addition," *Infect & Immun.* 61:384-390 (1993)
	C-20	Dertzbaugh, M.T. et al., "Comparative Effectiveness of the Cholera Toxin B Subunit and Alkaline Phosphatase as Carriers for Oral Vaccines,"*Infect & Immun.* 61:48-55 (1993)
	C-21	Dickinson et al., "Dissociation of Escherichia coli heat-labile enterotoxin adjuvanticity from ADP-ribosyltransferase activity," *Infect. & Immun.* 63:1617-1623 (1995)
	C-22	Domenighini et al., "Common features of the NAD-binding and catalytic site of ADP-ribosylating toxins," *Mol. Microbiol.* 14(1):41-50 (1994)
	C-23	Domenighini et al., "Identification of errors among database sequence entries and comparison of correct amino acid sequences for the heat-labile enterotoxins of Escherichia coli and Vibrio cholerae," *Mol. Microbiol.* 15(6):1165-1167 (1995)
	C-24	Donta, S., "Detection of Heat-Labile *Escherichia coli* Entertoxin With the Use of Adrenal Cells in Tissue Culture," *Science* 183:334-336 (1974)
	C-25	Douce et al., "Genetically Detoxified Mutants of Heat-Labile Toxin from *Escherichia coli* Are aBle to Act as Oral Adjuvants," *Infection and Immunity* 67(9):4400-4406 (1999)
SD	C-26	Ellis, Ronald W., "New Technologies for Making Vaccines," Chapter 29 pages 568-575 *Vaccines,* Plotkin & Mortimer

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Exam. Init.	Ref. Desig.	Description
SD	C-27	Giannini et al., "The Amino-Acid Sequence of Two Non-Toxic Mutants of Diphtherin Toxin: CRM45 and CRM197," *Nucleic Acid Res.* 12(10):4063-4069 (1984)
	C-28	Giuliani et al., "Mucosal Adjuvanticity and Immunogenicity of LTR72, a Novel Mutant of *Escherichia coli* Heat-Labile Enterotoxin with Partial Knockout of ADP-ribosyltransferase Activity," *J. Exp. Med.* 187(7):1123-1132 (1998)
	C-29	Grant, C.C.R., et al., "Effect of Single Amino Acid Changes on the ADP-Ribosyltransferase Activity of *Escherichia coli* Heat-Labile Toxin Subunit A," 92nd Gen. Meet. Am. Soc. Microbiol., 1992, Abstract B289, 74
	C-30	Grant et al., "Role of Trypsin-Like Cleavage at Arginine 192 in the Enzymatic and Cytotonic Activities of *Escherichia coli* Heat-Labile Enterotoxin," *Infection & Immununity* 62(10):4270-4278 (1994)
	C-31	Gupta et al., "Adjuvants-A Balance Between Toxicity and Adjuvanticity," *Vaccines* 11(13):294-305 (1993)
	C-32	Hagiwar et al., "Effectiveness and Safety of Mutant *Escherichia coli* Heat-Labile Enterotoxin (LT H44A) as an Adjuvant for Nasal Influenza Vaccine," *Vaccine* 19:2071-2079 (2001)
	C-33	Hartman et al., "Native and Mutant Forms of Cholera Toxin and Heat-Labile Enterotoxin Effectively Enhance Protective Efficacy of Live Attenuated and Heat-Killed *Shigella* Vaccines," *Infect. Immun.* 67(11):5841-5847 (1999)
	C-34	Häse et al., "Construction and Characterization of Recombinant *Vibrio Cholera* Strains Producting Inactive Cholera Toxin Analogs," *Infection and Immunity* 62(8):3051-3057 (1994)
	C-35	Hirst et al., "Transient Entry of Enterotoxin Subunits int the Periplasm Occurs During Their Secretion from *Vibrio cholera*," *J. Bacteriol.* 169(3):1037-1045 (1987)
	C-36	Holmgren, J. et al., "Oral Immunization Against Cholera," *Curr. Top. Microbiol. Immunol.* 146:197-204 (1988)
SD	C-37	Holmgren et al., "Strategies for the Induction of Immune Responses at Mucosal Surfaces Making Use of Cholera Toxin B Subunit as Immunogen, Carrier, and Adjuvant," *Am. J. Trop. Med. Hyg.* 50(5)Suppl.:42-54 (1994)

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Exam. Init.	Ref. Desig.	Description
SD	C-38	Holmgren et al., "Development of Improved Cholera Vaccine Based on Subunit Toxoid," *Nature* 269:602-604 (1977)
	C-39	Holmgren, "From Cholera Toxin to Subunit Vaccines," *Current Science* 59(13-14):665-669 (1990)
	C-40	Hörnquist, et al., "Cholera Toxin Adjuvant Greatly Promotes Antigen Priming to T Cells," *European Journal of Immunology*, 23(9):2136-2143 (1993) (abstract only)
	C-41	Houghten, "Relative Importance of Position and Individual Amino Acid Residues in Peptide Antigen-Antibody Interactions: Implications in the Mechanism of Antigenic Drivt and Antigenic Shift," *Vaccines* 86:21-25 (1986)
	C-42	Jakobsen et al., "Intranasal Immunization with Pneumococcal Polysaccharide Conjugate Vaccines with Nontoxic Mutants of *Escherichia coli* Heat-Labile Enterotoxins as Adjuvants Protects Mice Against Invasive Pneumococcal Infections," *Infection and Immunity* 67(11):5892-5897 (1998)
	C-43	Jobling et al., "Analysis of the Structure and Function of Cholera Toxin A Subunit," Abstr. Gen. Meet. Am. Soc. Microbiol. 91(0):p59, Abstract #B205
	C-44	Kaslow, H.R. et al., "Effects of Site-Directed Mutagenesis on Cholera Toxin A1 Subunit ADP-Ribosytransferase Activity," 92nd Gen. Meet. Am. Soc. Microbiol., 1992, Abstract B291, 74
	C-45	Kaslow et al., "Site-Specific Mutagenesis of the Pertussis Toxin S1 Subunit Gene: Effects of Amino Acid Substitutions Involving Residues 50-58," *Vaccine Research* 1(1):47-54 (1992)
	C-46	Lai, C.Y. et al., "Location and Amino Acid Sequence Around ADP-Ribosylation Site in the Cholera Toxin Active Subunit A," *Biochem. Biophys. Res. Comm.* 116(1):341-348 (1983)
	C-47	Langer, "New Methods of Drug Delivery," *Science* 249:1527-1533 (1990)
SD	C-48	Lebacq-Verheyden, A.M. et al., "Posttranslation Processing of Endogenous and the Baculovirus-Expressed Human Gastrin-Releasing Peptide Precursor," *Mol. Cell Biol.* 8:3129-3135 (1988)

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Exam. Init.	Ref. Desig.	Description
SD	C-49	Lebens et al., "Large-Scale Production of *Vibrio Cholera* Toxin B Subunit for Use in Oral Vaccines," *Biotechnol.* 11:1574-1578 (1993)
	C-50	Lebman et al., "Intraduodenal Application of Cholera Holotoxin Increases the Potential of Clones from Peyer's Patch B Cells of Relevant and Unrelated Specificities to Secrete IgG and IgA," *Regional Immun.* 1:32-40 (1988)
	C-51	Liang, X. et al., "Oral Administration of Cholera Toxin-Sendai Virus Conjugate Potentiates Gut and Respiratory Immunity Against Sendai Virus," *J. Immunol.* 141(5):1495-1501 (1988)
	C-52	Lobet et al., "Effect of Site-Directed Mutagenic Alterations of ADP Ribosyltransferase Activity of the A Subunit of *Escherichia coli* Heat-Labile Enterotoxin," *Infect. & Immun.*, 59:2870-2879 (1991)
	C-53	Loosmore et al., "Engineering of Genetically Detoxified Pertussis Toxin Analogs for Development of a Recombinant Whooping Cough Vaccine," *Infect Immun.* 58(11):3653-3662 (1990) (abstract only)
	C-54	Lycke et al., "The Mechanism of Cholera Toxin Adjuvanticity," *Res. Immunol.* 148:504-520 (1997)
	C-55	Marchetti et al., "Protection Against *Helicobacter pylori* Infection in Mice by Intragastric Vaccination with *H. pylori* Antigens is Achieved Using a Non-Toxic Mutant of *E. coli* Heat-Labile Enterotoxin (LT) as Adjuvant," *Vaccine* 16(1):33-37 (1998)
	C-56	Matousek et al., "Distinct Effects of Recombinant Cholera Toxin B Subunit and Holotoxin on Different Stages of Class II MHC Antigen Processing and Presentation by Macrophages," *J. Immunol.* 156:4137-4145 (1996)
	C-57	McKenzie et al., "Cholera Toxin B Subunit as a Carrier Protein to Stimulate a Mucosal Immune Response," *J. Immunol.* 133(4):1818-1824 (1984)
	C-58	Mekalanos, J.J. et al., "Cholera Toxin Genes," Nucleotide Sequence, Deletion Analysis and Vaccine Development," *Nature* 306:551-557 (1983)
SD	C-59	Mekalanos, "Production and Purification of Cholera Toxin, *Methods Enzymol.* 165:169-175 (1988)

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Exam. Init.	Ref. Desig.	Description
SD	C-60	Okamoto et al., "Effect of Subtitution of Glycine for Arginine at Position 146 of the A1Subunit on Biological Activity of *Escherichia coli* Heat-Labile Enterotoxin," *J. Bacteriol.* 170(5):2208-2211 (1988)
	C-61	"Oral Cholera Vaccines" *The Lancet* 328(8509):722-723 (1986)
	C-62	Oseasohn, R. "Cholera", In Plotkin SA, Mortimer EA eds. Vaccines, Philadelphia, WB Saunders Co. pp 362-371 (1988)
	C-63	Ott et al., in: Vaccine Design: The Subunit & Adj. Approach eds. Powell et al. pp. 277-295 1995
	C-64	Pearson et al., "Molecular Cloning of Vibrio Cholera Enterotoxin Genes in *Escherichia coli* K-12," *Proc. Natl. Acad. Sci. U.S.A.* 79:2976-2980 (1982)
	C-65	Pickett, C.L. et al., "Genetics of Type IIa Heat-Labile Enterotoxin of *Escherichia coli*: Operon Fusions, Nucleotide Sequence, and Hybridization Studies," *J. Bacteriol.* 169(11):5180-5187 (1987)
	C-66	Pierce et al., "Procholeragenoid: A Safe and Effective Antigen for Oral Immunization Against Experimental Cholera," *Infection and Immunity* 40(3):1112-1118 (1963)
	C-67	Pizza et al., "The Subunit S1 is Important for Pertussis Toxin Secretion," *J. Biol. Chem.* 265(29):17759-17763 (1990)
	C-68	Pizza et al., "A genetically detoxified derivative of heat-labile Escherichia coli enterotoxin induces neutralizing antibodies against the A subunit," J. Exp. Med. 180:2147-2153 (1994)
	C-69	Pronk et al., "Heat-Labile Enterotoxin of *Escherichia coli*," *J. Biol. Chem.* 260(25):13580-13587 (1985)
	C-70	Rappaport et al., "Development of Purified Cholera Toxoid I. Purification of Toxin," *Infect. Immun.* 9(2):294-303 (1974)
	C-71	Rappuoli et al., "Structure and evolutionary aspects of ADP-ribosylating toxins," *Sourcebook of Bacterial Toxins*, Academic Press Limited, pp1-21 (1991)
SD	C-72	Rappuoli et al., "Genetic Detoxification of Bacterial Toxins: A New Approach to Vaccine Development," *Inter. Arch. Allergy & Immunol.* 108:327-333 (1995)

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Exam. Init.	Ref. Desig.	Description
SD	C-73	Rappuoli et al., "Structure and Mucosal Adjuvanticity of Cholera and Escherichia coli Heat-Labile Enterotoxins," *Immunol. Today* 20:493-500 (1999)
	C-74	Roberts et al., "A mutant pertussis toxin molecule that lacks ADP-ribosyltransferase activity, PT-9K/129G, is an effective mucosal adjuvant for intranasally delivered proteins," *Infect. & Immun.* 63:2100-2108 (1995)
	C-75	Rodighiero et al., "Structural basis for the differential toxicity of cholera toxin and Escherichia coli heat-labile enterotoxin,"*J. Biol. Chem.* 274(7):3962-3969 (1999)
	C-76	Sanchez, J. et al., "Recombinant Cholera Toxin B Subunit and Gene Fusion Proteins Oral Vaccination," *Res. Microbiol.* 141:971-979 (1990)
	C-77	Sandkvist et al., "Assembly of Escherichia coli Heat-labile Enterotoxin and its Secretion From *Vibrio Cholerae*," *Molecular Mechanisms of Bacterial Virulence,* Chapter 21, pp 293-309 (1993)
	C-78	Sixma, T.K. et al., "Crystal Structure of a Cholera Toxin-Related Heat-Labile Enterotoxin from *E. Coli*," *Nature* 351:371-377 (1991)
	C-79	Spangler, "Structure and Function of Cholera Toxin and the Related *Escherichia coli* Heat-Labile Enterotoxin," *Microbiological Reviews* 56(4):622-547 (1992)
	C-80	Spicer, E.K. et al., "*Escherichia coli* Heat-Labile Enterotoxin," *The Journal of Biological Chemistry* 257:5716-5721 (1982)
	C-81	Spicer et al., "Sequence Homologies Between A Subunits of *Escherichia coli* and Vibrio *Cholerae* Enterotoxins," *Proc. Natl. Acad. Sci. U.S.A. 78*(1):50-54 (1981)
	C-82	Streatfield et al., "Intermolecular Interactions Between the A and B Subunits of Heat-Labile Enterotoxin from *Escherichia coli* Promote Holotoxin Assembly and Stability *in vivo*," *Proc. Natl. Acad. Sci. U.S.A.* 89:12140-12144 (1992)
	C-83	Sultzer et al., "The Adjuvant Effect of Pertussis Endotoxin Protein in Modulating the Immune Response to Cholera toroid in Mice," Proceedings of the Fourth Intl. Symposium on Pertussis, Joint IABS/WHO Meeting, Geneva Switzerland, 1984 Develop. in biol. Stand. 61:225-232 (1985)
SD	C-84	Torres et al., "*Clostridium Difficile* Vaccine: Influence of Different Adjuvants and Routes of Immunization on Protective Immunity in Hamsters," *Vaccine Research* 5(3):149-162 (1996)

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Sheet 11 of 11

In the Application of BARCHFELD et al. Confirmation No. 8826

Serial No.: 09/044,696 Art Unit: 1645

Filed March 18, 1998 Examiner: DEVI, SARVAMANGALA J N

Title: DETOXIFIED MUTANTS OF BACTERIAL ADP-RIBOSYLATING TOXINS AS PARENTERAL ADJUVANTS

Exam. Init.	Ref. Desig.	Description
SD	C-85	Tsuji, T. et al., "Relationship Between a Low Toxicity of the Mutant A Subunit of Enterotoxigenic *Escherichia coli* Enterotoxin and its Strong Adjuvant Action," *Immunology* 90:176-182 (1997)
	C-86	Vadolas et al., "Intranasal Immunization with Liposomes Induces Strong Mucosal Immune Responses in Mice," *Eur. J. Immunol.* 25:969-975 (1995)
	C-87	Verweij et al., "Musosal Immunoadjuvant Activity of Recombinant Escherichia coli Heat-Labile Enterotoxin and ♭ Subunit: Induction of Systemic IgG and Secretory IgA Responses in Mice by Intranasal Immunization with Influenza Virus Surface Antigen," *Vaccine* 16(20):2069-2076 (1998)
	C-89	Walker et al.. "Use of Heat-Labile Toxin of Enterotoxigenic *Escherichia coli* to Facilitate Mucosal Immunization," *Vaccine Res.* 2(1):1-10 (1993)
	C-90	Warren et al., "Current status of immunological adjuvants," *Ann. Rev. Immun.* 4:369-388 (1986)
	C-91	Yamamoto et al., "Mutants in the ADP-Ribosyltransferase Cleft of Cholera Toxin Lack Diarrheagenicity but Retain Adjuvanticity," *J. Exp. Med.* 185(7):1203-1210 (1997)
	C-92	Yamamoto, T. et al., "Primary Structure of Heat-Labile Enterotoxin Produced by *Escherichia coli* Pathogenic for Humans," *J. Biol. Chem.* 259:5037-5044 (1984)
YSD	C-93	Zoller et al., "Oligonucleotide-Directed Mutagenesis Using M13-Derived Vectors: an Efficient and General Procedure for the Production of Point Mutations in any Fragment of DNA," *Nuc.Acid Res.* 10(20):6487-6500 (1982)

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